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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,881	06/20/2003	John S. Brandstetter	P0010169.00	6677

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,881	BRANDSTETTER ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/19/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 13-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5, 6, 14, 15, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2 and 6, "is adjusted" is in the passive voice and is not positively reciting a method step. It is suggested to use active voice, such as "further comprising adjusting the sensing threshold...".

In claim 5, "to at least one pre-detection criteria" is vague since it is unclear if this is the same as the onset detection criteria used in claim 1.

In claims 14 and 18, the claims are vague since they do not set forth what element is performing the adjustment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nau et al (5732708) in view of Paul et al (5944744). Nau describes the use of his system in an implantable cardiac medical device (e.g. col. 1, line 8) using trigger events to trigger the storage of EGM data such as QRS complexes and depolarizations (e.g. col. 3, lines 10-15), along with the initial diagnosis of fibrillation or tachyarrhythmia, therapy delivered or aborted, etc (e.g. col. 13, lines 24-44, col. 8, lines 30-50, col. 9, lines 60-67) and that data is stored when the trigger event (onset of detection of an arrhythmia) is detected and stops the collection of data when the trigger event has been terminated (e.g. col. 12, lines 1-15). Nau also discloses that this data is telemetered out to an external programmer where the physician uses the data to tweak the IMD settings or parameters (e.g. col. 3, lines 32-40, col. 8, lines 16-20) and therefore provides motivation to have the external programmer/physician modify device settings.

But Nau does not specifically disclose the IMD has a sense amplifier that detects cardiac signals with intrinsic heart depolarizations that exceed a threshold, using those senses for processing for detection/onset/pre-detection of tachyarrhythmia, storing and transmitting data "representing" the peak amplitudes to an external device, and having the external device adjusting the sensing threshold to ensure sensing. Paul discloses an IMD (e.g. col. 1) that has a sense amplifier that detects cardiac signals with intrinsic heart depolarizations that exceed a threshold, transmitting data "representing" the peak amplitudes to an external device (e.g. col. 4,

lines 57-59) and having the external device adjust the sensitivity/sensing thresholds to ensure sensing (e.g. col. 3, lines 58-60, col.8, line 46 and on), all to provide optimal sensitivity for detecting and processing the patient's cardiac signal and allow the physician to place limits on the sensitivity changes and/or provide the correct sensing threshold. Paul also states that it is known that during onset and progression of tachycardia and fibrillation that the amplitude of the electrical events varies widely and means are needed to cope with the amplitude variations, such as changing thresholds (e.g. col. 3).

It would have been obvious at the time the invention was made to incorporate in the IMD method and system as taught by Nau, the use of a sense amplifier that detects cardiac signals with intrinsic heart depolarizations that exceed a threshold, transmitting data representing the peak amplitudes to an external device, and having the external device adjust the sensing thresholds to ensure sensing as taught by Paul, since such a modification would provide an IMD method and system with a sense amplifier that detects cardiac signals with intrinsic heart depolarizations that exceed a threshold, transmitting data representing the peak amplitudes to an external device, and having the external device adjust the sensing thresholds to ensure sensing, all to provide the predictable results of having optimal sensitivity for detecting and processing the patient's cardiac signal and allow the physician to place limits on the sensitivity changes and/or to provide the correct sensing threshold.

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD system and method as taught by Nau or Nau in view of Paul, with the use of the sensed intrinsic events for processing for detection/onset/pre-detection of tachyarrhythmia since it was known in the art that IMD methods and systems use the

sensed intrinsic events, such as R and P waves, for processing for detection/onset/pre-detection of tachyarrhythmia to provide the predictable results of allowing the IMD to conventionally and easily determine when the heart rate has exceeded criteria for indicating fibrillation or tachycardia and delivering appropriate therapy to treat the arrhythmia.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The argument that Nau does not measure detected peak amplitudes is not persuasive since Paul is provided to show this limitation. Paul stores, measures, and detects the peak amplitudes using an outer target reference signal which is an indication of the peak amplitude of the cardiac signal (e.g. col. 4, line 57). In addition, Nau measures the peak amplitudes since he senses the EGM and stores data representative of the EGM, which inherently has peak amplitudes (i.e. R waves). The argument that Paul does not detect, measure and store signal peaks is not persuasive as discussed above. The argument that Paul does not stop the sensing when the episodes ends and continuously senses the signals is not persuasive since Nau was used to provide this claim limitation. Nau teaches the starting and stopping of the storage of the data upon onset/termination of the arrhythmia. In addition, the claim is a comprising claim, an open ended claim, and does not preclude the use of sensing at other times. The argument that Paul does not adjust the sensing threshold is not persuasive. Paul teaches in column 3, lines 58-60 that it is known for the physician to adjust the sensing threshold. In addition, Paul changes the sensitivity control, which is a sensing threshold that is used to indicated cardiac events (e.g. col. 4, col. 7, line 65 to col. 8, line 6, etc.).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hsu teaches the use of peak amplitudes, sense amplifiers, and association of therapy delivered.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762
9/14/07

GRE
9/14/07